C.A.T.S. - Children Afflicted By Toxic Substances
Jama Russano
413 Fort Salonga Road
Northport, NY 11768
Ph: 631-757-4829

To: Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket Number 2004D-0002

April 12, 2004

Dear FDA,

Over the last 12 years it has become clear that silicone and secondary chemicals used in breast implants are a health risk to: Young Women, Women of child bearing years and to a Fetus. Before Surgical Device's are approved for Plastic Surgery Implantation, Manufacturers must conduct Clinical Trials to evaluate the health risks on the following:

a.) Young women - ages 13 to 21: What are the health effects on a young growing body. Do silicone gel/oils along with secondary chemicals cause Endocrine Disorders? Have adverse impact on growing bones, etc... Is a young woman more promiscuous? Exposing her to HIV and Pregnancy?
b.) Emotional Health (before and after implant surgery). Are young women capable of understanding that breast implants are a life time of surgeries, that there is no turning back? Is it made clear that if an adverse problem occurs that they must pay for their health care? Can young women understand and make the determination that she may not be able to breast feed. Is a mother able to live with the guilt, that; a.) She is sick and unable to take care of her family b.) She made her child(ren) sick?

c.) Women of child bearing age: What are the hormonal effects? Have their immune systems been compromised? Are they more propone to infertility, miscarriages, and pregnancy problems such as placenta previa? Are they getting Cancer and Auto Immune Diseases at an early age?

d.) Understanding the risks (before the surgery): It needs to be documented (If women had the opportunity to go through the surgery over again, knowing and experiencing the implants, would they have made the decision not to have had the surgery? Looking back, do they feel they were given all the information they needed to make an informed decision)?

e.) The ability to breast feed after implant surgery: Women's nerve endings are cut, milk ducts are blocked during implant surgery. Many are unaware of these problems and many do not know if they want to breast feed. It must be identified how many are effected by this type of procedure.

e.) Health Risks of Breast feeding (silicone and secondary chemicals passing through milk ducts): Do silicone gel/oils and secondary chemicals migrate through the milk ducts, exposing a new born to undeveloped esophagus? How, much of these chemicals get through and what are the health effects.

f.) What are the overall health effects on children (short and long term, regardless of breast feed or bottle feed): Does silicone gel/oils and secondary chemicals cross the placenta barrier, exposing the developing fetus to various chemicals. Do the chemicals used in the manufacture of breast implants Endocrine Disrupters? Do children grow out of their health problems? How many children are exposed? Are the ill effects life time? Are they experencing bone and growth

problems?

g.) All children born to a mother with an implant must be followed short and long term, far past a 10 year period.

h.) Identifying First (silicone) and Secondary Chemicals (platinum, benzene, etc.): The FDA, Physicians and the consumer must have access to the combination of chemicals that are used in the devices. Chemicals such as Phthalates are used in manufacturing. When combined with other chemicals it could pose various health problems to a human.

i.) Long term health effects on children (physical and emotional). Once again, long term studies should be conducted. It has been reported that many children exposed to a breast implant show signs of ADD, low or high hormone levels. What is the emotional impact a child has, once a child learns that he/she has been exposed to their mother's implants?

j.) Third Generation: Can a child exposed to implants "via in-utero", cause harm to their children? What happens when two adults exposed to implants have children?

k.) It has been stated that the FDA has no funding for Med Watch. It is also clear that once a product is on the market, it is vary hard to get the product off. If a device is approved, for market and the number of Patients with complaints should be equal to the number of persons studied in the trial. The device should go on probation until further evaluation can be done. The FDA must bring more funding to the Med-Watch Program and the program be properly monitored.

To get a clear understanding on all health risks and safety factors associated with all types of plastic surgery devices including silicone and saline breast implants, Retrospective studies outlining the above should be conducted on the hundreds of thousands of young women and children. These issues have been avoided far too long.

We have also learned that there is no substitute for properly conducted prospective clinical trials. Post-market surveillance and postapproval conditions are of little value to women considering breast implants after approval. Further, we have learned of many instances where women have been unable to report medical problems to the FDA through the MedWatch system and that the FDA rarely considers the large number of adverse events reported through the post-market surveillance system. For these reasons, the FDA must ensure that long-term safety is addressed prior to approval.